

REMARKS**1. The Amendments and the Support Therefor**

No claims have been canceled, five new claims (71-75) have been added, and claims 51, 56, 61-64, and 68 have been amended to leave claims 51, 53, 55-64, 67, 68, and 70-75 in the application. No new matter has been added by the amendments or new claims, wherein:

- ***Claims 51, 64, 72:*** Find support at (for example) FIG. 2 (see examples 4, 5, and 6, wherein the central resilient member has a cross-sectional area sized the same as, or slightly greater than, the first and second parts on the opposite sides of the central resilient member when the first and second parts are in their open configurations).
- ***Claims 56, 61:*** Find support at (for example) FIG. 2.
- ***Claim 62:*** Is amended to independent form, with its parent claim 51 being incorporated.
- ***Claim 63:*** Finds support at (for example) FIG. 3.
- ***Claims 64, 68, 74, 75:*** Find support at (for example) FIG. 2 (see examples 4, 5, and 6, wherein the first parts on one side of the central resilient member are aligned in abutment, and the second parts on the other side of the central resilient member are aligned in abutment).
- ***Claims 64, 71, 73:*** Find support at (for example) FIG. 2 (see examples 4, 5, and 6, wherein the central resilient member is coaxial with the first and second parts on the opposite sides of the central resilient member).

2. Sections 2-3 of the Office Action: Rejection of Claim 63 under 35 USC §112(2)

Claim 63 is amended to eliminate the artery/vein as a portion of the claimed invention.

3. Sections 4-5 of the Office Action: Rejection of Claims 51, 53, 55-61, 63, 64, 67, 68, and 70 under 35 USC §102 in view of U.S. Patent 6,994,713 to Berg

Berg describes a connector (or plug) structure whose primary characteristics are described at column 2 lines 3-35, and are shown in FIGS. 4-5:

These and other objects of the invention are accomplished in accordance with the principles of the invention by providing a connector or plug structure preferably formed by starting from a tube of highly elastic material such as nickel and titanium alloy (nitinol) metal. Each end portion of the tube is cut substantially axially at numerous locations spaced circumferentially around the tube to produce a plurality of fingers that extend substantially axially from each end of a remaining medial portion of the tube. The fingers at each end of the medial portion are then deflected so that

they extend substantially radially out from the medial portion, and the fingers are set (e.g., by a heat treatment) in that deflected condition. For use of the structure as a graft connector, the medial portion is attached substantially coaxially to an end portion of a graft conduit. For use of the structure as a plug the medial portion of the tube is filled with a suitable plugging material or structure.

To install the graft connector or plug in a patient the fingers at each axial end of the medial portion may be elastically deformed back toward their initial condition (in which the fingers extend substantially axially from the ends of the medial portion). The structure may then be inserted in a delivery tube, which may maintain the fingers in their substantially axially extending condition. The delivery tube may then be inserted through the aperture in the side wall of the patient's tubular body conduit to which the end of the graft conduit is to be attached, or through the aperture in the patient's tissue structure that is to be plugged. The delivery conduit may then be removed from around the connector or plug structure. This releases the fingers at each end of the medial portion to spring out on respective opposite sides of the tissue structure to which the connection is to be made, or to which the plug is to be applied.

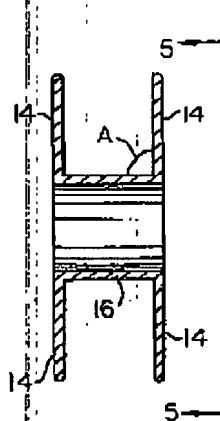


FIG. 4

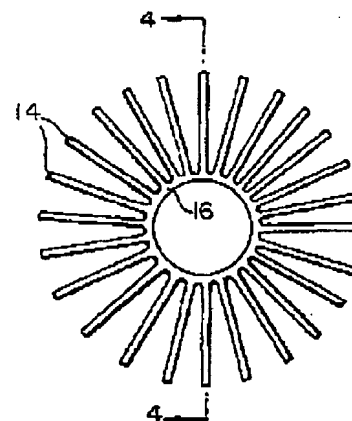


FIG. 5

Installation of the *Berg* connector is then shown in FIGS. 7-8 and discussed at column 6 line 58 onward. A hole is cut in a vessel, and the medial portion 16 is then inserted in the hole with one of the sets of fingers 14 grasping one side of the vessel, and the other set of fingers 14 grasping the other side of the vessel:

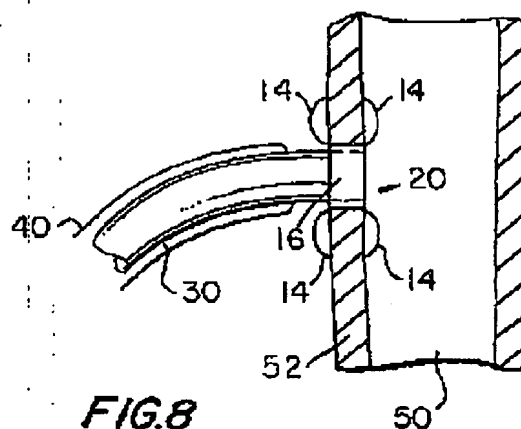
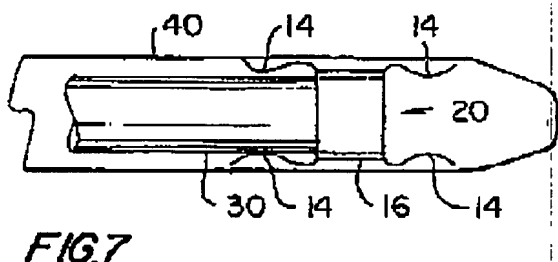


FIG. 13, discussed at column 7 line 28 onward, shows that the medial tubular portion 16 of the connector can be perforated.

FIG. 14, discussed at column 8 line 20 onward, describes how the ends of fingers 14 may be sharpened to penetrate tissue.

FIG. 15, discussed at column 8 line 27 onward, shows a connector 20 wherein one of the sets of fingers 14 is elongated and bears a barb 14b so that it may pierce a vessel wall.

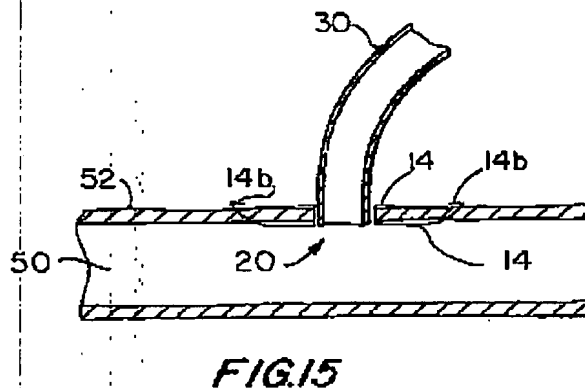


FIG. 18, discussed at column 9 line 15 onward, shows a connector wherein the fingers 14 are "cylindrically curved" so that the tips of one of the sets of fingers 14 curve towards the tips of the other set of fingers 14.

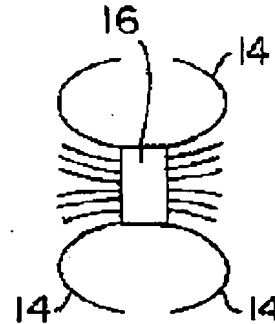


FIG. 18

FIG. 22, discussed at column 9 line 25 onward, shows how such a connector may be used to affix a graft adjacent a hole in a wall.

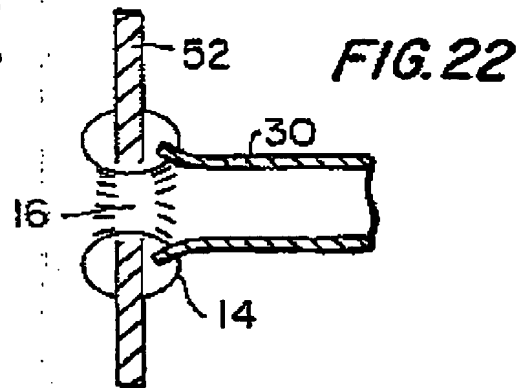


FIG. 22

Independent claim 51 is amended to recite that the resilient member has a cross-sectional area at least substantially equal to the greater of (1) the cross-sectional area of the first parts, and (2) the cross-sectional area of the second parts. Looking to FIG. 7 of *Berg* (or FIGS. 10, 11, 19, etc.), wherein *Berg* is shown in its open configuration, it is seen that *Berg*'s "resilient member" 16 always has a (very) significantly greater cross-sectional area than the first and second parts (the sets of "fingers" 14 on the opposing sides of the "resilient member" 16). Further, it would not be obvious to one of ordinary skill in the art to "shrink" the member 16 to have the same or similar diameter as the collected fingers 14. If this were done, *Berg* would no longer function for its intended purpose of splicing a graft into the wall of a vessel as shown in FIG. 8 of *Berg* (or FIGS. 15, 22, etc.). See MPEP 2143.01 (subsection entitled "The Proposed Modification Cannot Render The Prior Art Unsatisfactory For Its Intended Purpose"). Thus, if the prior art is objectively reviewed without prior

knowledge of the invention (i.e., without hindsight), it is seen that the teachings of the art do not lead one to the presently-claimed invention.

Regarding *dependent claim 56*, which recites that the device is formed of one or more wires extending along the length of the device, this structure is plainly not shown or suggested by *Berg*. The Office Action asserts that *Berg*'s medial tubular portion 16 could be "deemed a hollow wire," but this is not a reasonable interpretation of the term "wire": it cannot fairly be said that any ordinary artisan would regard *Berg*'s medial tubular portion 16 as being a "wire." It is accepted that during examination, the USPTO must interpret the claims using their broadest reasonable interpretation (MPEP 2111). Words in a claim are therefore given their plain meaning unless a contrary definition is provided in the specification (MPEP 2111.01). Further, the "plain meaning" to be applied to words in a claim is the meaning applied by those of ordinary skill in the art, *not* the meaning ascribed to the term by laymen or others (MPEP 2111.01). Extrinsic references such as dictionaries may provide evidence of the meaning of claim terminology, so long as the dictionary meanings are otherwise consistent with the Applicant's usage (MPEP 2111.01). While an interpretation wherein *Berg*'s medial tubular portion 16 is regarded as being a "wire" may be broad, it is not reasonable; *Berg* does not refer to it as a wire, and no dictionaries or other sources provide any definitions of "wire" which encompass structures such as *Berg*'s medial tubular portion 16. If the rejection is maintained, kindly provide support for any assertion that *Berg*'s medial tubular portion 16 would truly be considered a "wire" by one of ordinary skill.

Regarding *dependent claim 61*, which recites that the device is formed of a plurality of wires, this structure is not shown or suggested by *Berg*, nor would one of ordinary skill regard such structure to be obvious in view of *Berg*. *Berg*'s medial tubular portion 16 is not formed of wire, nor is it in any way apparent how *Berg*'s medial tubular portion 16 could be formed of wire with any reasonable expectation of success.

Claim 62 was indicated as being allowable if amended to incorporate the matter of its parent claim, and since claim 62 has been so amended, it should now be allowable.

Independent claim 64 is submitted to be allowable for reasons similar to those for independent claim 51 (discussed above), in that it recites that the fixator has an at least substantially uniform cross-sectional area as it extends from its first parts to its second parts. This arrangement is not present in *Berg* owing to the enlarged cross-section of member 16 versus the smaller cross-sectional area of the parts 14, and cannot be accommodated by *Berg* if *Berg* is to function for its intended purpose of splicing a graft into the wall of a vessel (e.g., as shown in FIG. 8). Claim 72, dependent from claim 68, is submitted to be allowable for at least the same reasons.

Further, claim 64 also recites that the first parts and second parts of the elongated members are all at least substantially coaxial when the elongated members are in their open configuration. This arrangement is also not present in *Berg*, wherein numerous first parts (i.e., the parts 14 on one side of the central member 16) have their axes spaced apart by the central aperture within member 16, and the same is true of numerous second parts (i.e., the parts 14 on the other side of the central member 16). Again, the recited arrangement cannot be accommodated without "shrinking" the central aperture of member 16 of *Berg* until it disappears, but such a modification would render *Berg* inoperative for its intended purpose. Claim 71, dependent from claim 68, and claim 73, dependent from claim 51, are submitted to be allowable for the same reasons.

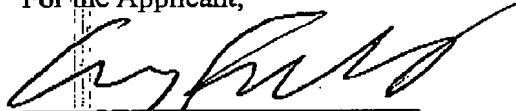
In addition, claim 64 is submitted to be allowable for the same reasons as independent claim 68, discussed below.

Independent claim 68 now recites that the first parts are adjacently situated in abutment (as are the second parts) when the fixator is in its open configuration, an arrangement which is not found in *Berg*. See, for example, FIG. 7 of *Berg*, wherein the first parts 14 on one side of the central member 16 are spaced by the central aperture within member 16, as are the second parts 14 on the opposite side of the central member 16. Here too, the recited arrangement cannot be accommodated without eliminating the central aperture of member 16 of *Berg*, a step which renders *Berg* inoperative for its intended purpose. Claims 74 and 75, dependent from claim 51, are submitted to be allowable for the same reasons.

4. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



Craig A. Fieschko, Reg. No. 39,668
DEWITT ROSS & STEVENS, S.C.
Firststar Financial Centre
8000 Excelsior Drive, Suite 401
Madison, Wisconsin 53717-1914
Telephone: (608) 828-0722
Facsimile: (608) 831-2106
cf@dewittross.com